

APPENDIX BUNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO.
09/738,147	12/15/2000	Howard Kaufman	MDS-013B	1850

21323 7590 10/21/2002

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EXAMINER

STAFIRA, MICHAEL PATRICK

ART UNIT

PAPER NUMBER

2877

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/738,147

Applicant(s)

KAUFMAN ET AL

Examiner

Michael P. Stafira

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply****A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 18-34 is/are allowed.
- 6) ☐ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner
If approved, corrected drawings are required in reply to this Office action
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4-7.

- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Drawings

1 This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed

Claim Rejections - 35 USC § 102

2 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action.

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3 Claims 1-8, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Pugliese ('020).

Claim 1

Pugliese ('020) discloses dispensing a plurality of chemical agents on a tissue (See Abstract), wherein the chemical agents interact to alter an optical signal produced by the tissue (Col. 4, lines 15-20), measuring the altered optical signal (Col. 4, lines 28-32), and providing a diagnosis based upon the altered optical signal (Col. 4-5, lines 62-4).

Claim 2

Pugliese ('020) discloses dispensing a plurality of chemical agents on a tissue (See abstract), determining whether the chemical agents alter an optical signal produced by the tissue

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(Col. 4, lines 15-20), and providing a diagnosis based upon whether the optical signal is altered

(Col. 4-5, lines 62-4)

Claim 3

The reference of Pugliese ('020) further discloses the chemical agent interact to produce an additive effect on the optical signal (Col. 6, lines 16-23)

Claim 4

Pugliese ('020) further discloses the chemical agents interact to reduce an intensity of the optical signal (Col. 6, lines 59-65).

Claim 5

Pugliese ('020) further discloses that the optical signal is a light spectrum (fluorescence) (Col. 4, lines 15-20).

Claim 6

The reference of Pugliese ('020) further discloses the light spectrum is a fluorescent spectrum (Col. 4, lines 15-20).

Claim 7

Pugliese ('020) further discloses the optical signal is produced by an endogenous chromophore (Col. 4, lines 15-20).

Claim 8

Pugliese ('020) further discloses the endogenous chromophore is a fluorophore (Col. 4, lines 15-20).

Claim 12

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The reference of Pugliese ('020) further discloses that the optical signal is measured over a predetermined time (See Fig. 6).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9-11, 13, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pugliese ('020).

Claim 9

Pugliese ('020) discloses the claimed invention except for a chemical agent selected from the group of acetic acid, formic acid etc. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Pugliese ('020) with one of the groups of chemicals, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416

Claims 10, 11

Pugliese ('020) discloses the claimed invention except for disclosing the chemicals are dispensed simultaneously or sequentially. It would have been obvious matter of design choice to combine Pugliese ('020) with dispensing of chemical agent simultaneously or sequentially, since applicant has not disclosed that dispensing the chemical agent simultaneously or sequentially

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solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the dispensing means disclosed in Pugliese ('020) (Col. 4, lines 35-39). It's the position of the examiner that the reference of Pugliese ('020) can dispense the chemical agents in any combination of order since the syringes are manipulated by hand

Claim 13

Pugliese ('020) discloses the claimed invention except for at least one member of the plurality of chemical agents alters pH of the sample. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the pH altering agent to the sample, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 14

Pugliese ('020) discloses the claimed invention except for the member is selected from the group consisting of osmotic agents and ionic agents. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Pugliese ('020) with the member consisting of osmotic agents and ionic agents, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

6. Claims 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Pugliese ('020)

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Claim 15

Pugliese ('020) discloses dispensing a chemical agent on the tissue (See Abstract), measuring a change in response to the chemical agent in an optical signal from an endogenous chromophore in the tissue (Col. 4, lines 15-20), and providing a diagnosis based upon the change (Col. 4-5, lines 62-4).

Claim 16

The reference of Pugliese ('020) further discloses the chromophore is a fluorophore (Col. 4, lines 15-20).

Claim 17

Pugliese ('020) further discloses the tissue is consisting of skin (Col. 4, lines 15-20)

Allowable Subject Matter

7. Claims 18-34 are allowed over the prior art of record.

8. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 18, the prior art fails to disclose or make obvious a method of diagnosing in a patient having the steps of providing an automated triggering signal to initiate a measurement period relative to the dispensing step and measuring a temporal evolution of the optical signal observed from the tissue during the measurement period, and in combination with the other recited limitations of claim 18. Claims 19-26 are allowed by the virtue of dependency on the allowed claim 18.

Regarding claim 27, the prior art fails to disclose or make obvious a method for diagnosing disease in a patient having the steps of capturing a plurality of sequential images of

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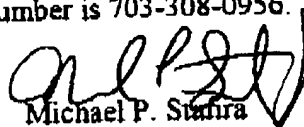
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the tissue during a measurement period and aligning a subset of the plurality of images to spatially correlate the subset and further measuring a temporal evolution of the optical signal from the subset of spatially correlated images, and in combination with the other recited limitations of claim 27 Claims 28-34 are allowed by the virtue of dependency on the allowed claim 27.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Stafira whose telephone number is 703-308-4837. The examiner can normally be reached on 4/10.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank Font can be reached on 703-308-4881. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7722 for regular communications and 703-308-7721 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.


Michael P. Stafira
Primary Examiner
Art Unit 2877

October 17, 2002